UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,827	03/07/2007	Kenneth Feldmann	2750-1573PUS1	5253

2292 7590 10/14/2011
BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
BAUM, STUART F	

ART UNIT	PAPER NUMBER
1638	

NOTIFICATION DATE	DELIVERY MODE
10/14/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/572,827	FELDMANN ET AL.	
	Examiner	Art Unit	
	STUART F. BAUM	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/1/2010 , 1/5/2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *10,13-15 and 17-23* is/are pending in the application.

5a) Of the above claim(s) *10 and 17* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *13-15 and 18-23* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *21 March 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed 11/1/2010 and the sequence listing filed 1/5/2011 have been entered.

2. Claims 10, 13-15 and 17-23 are pending.

Claims 1-9, 11-12 and 16 have been canceled.

Claims 21-23 have been newly added and are drawn to the elected invention.

Claims 10 and 17 are withdrawn from consideration for being drawn to a non-elected invention.

3. Claims 13-15 and 18-23, including SEQ ID NO:35 and 36 are examined in the present office action.

4. Rejections and objections not set forth below are withdrawn.

5. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 13-15 and 18-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims have been amended to recite "with a nucleic acid molecule which encodes an amino acid sequence exhibiting at least 95% sequence identity to SEQ ID NO:36; generating from said plant cell a transformed plant in which said nucleic acid molecule is overexpressed; and selecting from a plurality of said transformed plants a plant having at least one trait selected from the group consisting of delayed flowering time, an increase in plant height, an increase in inflorescence size, an increase in inflorescence thickness, an increase in the size of the rosette and an increase in rosette leaf number as compared to a control plant that does not comprise said nucleic acid molecule". Applicants point to pages 27-32 for support but no support for that phrase could be found. The recited location discloses SEQ ID NO:39 instead of SEQ ID NO:36 and the claimed traits are not disclosed for SEQ ID NO:36. Applicants are required to point to support for the amendment or to amend the claims to delete the NEW MATTER.

Written Description

7. Claims 13-15 and 18-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method of modulating flowering time or size of a plant or the size or number of rosette leaves of a plant comprising transforming a plant with a nucleic acid molecule encoding an amino acid sequence exhibiting at least 95% identity to SEQ ID NO:36, generating a plant from said plant cell and selecting a plant having at least one trait selected from

the group consisting of delayed flowering time, an increase in plant height, an increase in inflorescence size, an increase in inflorescence thickness, an increase in the size of the rosette and an increase in rosette leaf number as compared to a control plant that does not comprise said nucleic acid molecule; or a plant, plant cell, plant material or seed obtained from said method.

Applicants disclose SEQ ID NO:35 (sequence listing).

Applicants do not identify essential regions of the protein of SEQ ID NO:36, nor do Applicants describe any polynucleotide sequences that encode a polypeptide exhibiting at least 95% sequence identity to SEQ ID NO:36 wherein a plant transformed with said polynucleotide exhibits delayed flowering time, an increase in plant height, an increase in inflorescence size, an increase in inflorescence thickness, an increase in the size of the rosette or an increase in rosette leaf number.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the

genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of polynucleotide sequences encoding a protein falling within the scope of the claimed genus of polynucleotides which encode a polypeptide exhibiting at least 95% identity to SEQ ID NO:36, wherein a plant transformed with said polynucleotide exhibits delayed flowering time, an increase in plant height, an increase in inflorescence size, an increase in inflorescence thickness, an increase in the size of the rosette or an increase in rosette leaf number as compared to a control plant that does not comprise said nucleic acid molecule. Applicants only disclose SEQ ID NO:36. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for the protein of SEQ ID NO:36, it remains unclear what features identify the protein. Both the prior art and the specification fail to disclose a correlation between the structure of the claimed sequences and the recited function. Since the genus of proteins has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims.

Applicant's arguments filed 11/1/2010 have been fully considered but they are not persuasive.

Applicants contend the amendment to claims 13 and 14 now provide both structural and functional requirements for the claimed subject matter (page 9 of Remarks, 4th full paragraph).

The Office contends the rejection is maintained for the reasons stated above. Applicants have not disclosed a structure function relationship for the claimed genus of polynucleotides, i.e., a plant transformed with a polynucleotide falling within the scope of the claims produces a plant with the claimed phenotype.

Enablement

8. Claims 13-15 and 18-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to a method of modulating flowering time or size of a plant or the size or number of rosette leaves of a plant comprising transforming a plant with a nucleic acid molecule encoding an amino acid sequence exhibiting at least 95% identity to SEQ ID NO:36, generating a plant from said plant cell and selecting a plant having at least one trait selected from

the group consisting of delayed flowering time, an increase in plant height, an increase in inflorescence size, an increase in inflorescence thickness, an increase in the size of the rosette and an increase in rosette leaf number as compared to a control plant that does not comprise said nucleic acid molecule; or a plant, plant cell, plant material or seed obtained from said method or wherein the nucleic acid molecule encodes SEQ ID NO:36 or wherein the nucleic acid molecule is SEQ ID NO:35 .

Applicants disclose SEQ ID NO:35 and 36 (sequence listing).

Applicants have not reduced to practice the claimed invention. Applicants have not transformed any plant with a nucleic acid encoding SEQ ID NO:36 or wherein the nucleic acid is SEQ ID NO:35. Applicants have not transformed a plant with any of the polynucleotides encompassed within the genus of polynucleotides encoding a polypeptide exhibiting at least 95% identity to SEQ ID NO:36; nor have Applicants disclosed how one skilled in the art would use such a plant.

Applicants have not provided examples or guidance for selecting a sequence out of the multitude of sequences that are encompassed by Applicant's broad claim language that gives the expected results when transformed into a plant. Transforming plants with heterologous genes that are involved in plant development produce unpredictable results. Kano-Murakami et al (1993, FEBS 334:365-368) teach introducing the *Oryza sativa* homeobox 1 (OSH1) gene into tobacco. OSH1 is a rice homologue of the *Knotted-1* homeobox gene from maize and would be encompassed by Applicant's broad claim language. Kano-Murakami et al teach transgenic tobacco plants comprising the OSH1 gene display a "range of phenotypes which include

abnormalities in leaf and petal shape as well as stem height and number" (page 365, right column, 1st paragraph).

Applicants have not provided any teachings for one skilled in the art to predict and isolate nucleic acid sequences that encode a protein with the necessary activity to be operable in Applicants' invention. Applicants have not taught which regions of the respective polynucleotides can be used to amplify any of said polynucleotides or which regions can be used as a probe to isolate any of said polynucleotide sequences. Therefore, the instant specification fails to provide guidance for which amino acids of the protein of SEQ ID NO:36 can be altered, the type of alteration, and which amino acids must not be changed, to maintain activity of the encoded protein. The specification also fails to provide guidance for which amino acids can be deleted and which regions of the protein can tolerate insertions and still produce a functional protein.

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, either by using non-disclosed fragments of a sequence encoding a protein exhibiting 95% identity to SEQ ID NO:36 as probes or by designing primers to undisclosed regions of SEQ ID NO:36 and isolating or amplifying fragments, subcloning the fragments, producing expression vectors and transforming plants therewith, in order to identify those, if any, that when over-expressed produce a plant that exhibits delayed flowering time, an increase in plant height, an increase in inflorescence size, an increase in inflorescence thickness, an increase in the size of the rosette or an increase in rosette leaf number as compared to a control plant that does not

comprise said nucleic acid molecule and wherein the nucleic acid molecule encodes a protein exhibiting at least 95% identity to SEQ ID NO:36.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

Applicant's arguments filed 11/1/2010 have been fully considered but they are not persuasive.

Applicants contend the specification discloses the techniques required to practice the claimed invention (page 10 of Remarks, 1st and 2nd full paragraphs).

The Office contends that given the unpredictability in the art as stated above and given the level of skill required to practice the claimed invention and given the lack of teaching by way of disclosure or example of transforming a plant with any polynucleotide encoding a protein having at least 95% identity to SEQ ID NO:36, undue trial and error experimentation would be required to practice the claimed invention. See In re Fisher, 166 USPQ 18, 24 (CCPA 1970), which teaches that the allegedly pioneering nature of an invention does not obviate the need for "a reasonable correlation" between the scope of the claims and "the scope of enablement provided by the specification", wherein "the scope of enablement obviously varies conversely with the degree of unpredictability of the factors involved" in "cases involving unpredictable factors, such as most chemical reactions and physiological activities".

9. Claims drawn to a method of producing a transgenic plant and plant produced by said method comprising transforming a plant with a nucleic acid molecule encoding SEQ ID NO:36 or wherein the nucleic acid molecule is SEQ ID NO:35 is free of the prior art.

10. No claims are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Stuart F. Baum/
Stuart F. Baum Ph.D.
Primary Examiner
Art Unit 1638